

USAID Cooperative Agreement No. GHS-A-00-04-00016-00

Annual Report – 2004 Submitted by Program for Appropriate Technology in Health January 31, 2005

Executive Summary

PATH carried out the following activities from October through December 2004.

The agreement between PATH and USAID was signed on October 8, 2004. Subsequent conversations led to a defined scope of work and budget submitted November 23, 2004, and approved by USAID on December 3, 2004.

FMP-1 Phase 2b Clinical Trial

Per the approved scope of work and budget, a subagreement with Walter Reed Army Institute of Research (WRAIR) was established. Work on the FMP-1 Phase 2b clinical trial continues under this subagreement. No USAID funds were spent on this project prior to December 31, 2004, as an amended Cooperative Research And Development Agreement was still under negotiation. Two milestone payments will be disbursed in Q1 2005: \$926,131 due upon signing, and \$908,697 due March 31. The Investigational New Drug application for this product is on file at the U.S. FDA and the protocol is currently being reviewed by the various institutional review boards, including PATH's Human Subjects Protection Committee, WRAIR'S Human Subjects Research Review Board, and the Kenyon Medical Research Institute Ethical Review Committee. Screening of potential trial participants should commence by late February 2005, with first vaccinations in late March.

Malaria Vaccine Market Assessment

Also, per the approved scope of work and budget, PATH has entered into a subcontract with the Boston Consulting Group to conduct a comprehensive malaria vaccine market assessment. The assessment is complete and presentations on the results have been made in the U.S., Africa, and Europe. Feedback on the market assessment has been extremely positive. No USAID funds were spent on this project prior to December 31, 2004; however, a final payment will be made shortly.

Decision Making Framework

A Decision Making Framework, which constitutes the third part of the scope of work, is currently in the planning stages. Newly hired Policy Officer, Alan Brooks, will be leading this activity. Expenditures for this framework will begin soon.



No USAID funds were spent on this project in 2004due to the change in scope of work, a relocation of MVI's Rockville office to Bethesda, and the end-of-year holidays. All work necessary under the scope of work will be accomplished in 2005.

Financial Review

PATH's quarterly financial report will be submitted by January 31, 2005, per the agreement terms.